

United States Department of Agriculture  
Animal and Plant Health Inspection Service  
4700 River Road  
Riverdale, MD 20737

**Permit to Move Live Plant Pests, Noxious Weeds, and Soil**  
Interstate Movement  
**Regulated by 7 CFR 330**

This permit was generated electronically via the ePermits system

<b>PERMITTEE NAME:</b>	Dr. Heinrich Jasper	<b>PERMIT NUMBER:</b>	P526P-17-04609
<b>ORGANIZATION:</b>	Genentech, Inc	<b>APPLICATION NUMBER:</b>	P526-171010-015
<b>ADDRESS:</b>	1 DNA Way Room 12-268 South San Francisco, CA 94080	<b>FACILITY NUMBER:</b>	4592
<b>MAILING ADDRESS:</b>	1 DNA Way South San Francisco, CA 94080	<b>HAND CARRY:</b>	No
<b>PHONE:</b>	650-4671248	<b>DATE ISSUED:</b>	12/19/2017
<b>FAX:</b>		<b>EXPIRES:</b>	<b>12/19/2020</b>
<b>DESTINATION:</b>	Genentech Inc., 1 DNA Way, Room 12-268, South San Francisco, CA 94080		
<b>RELEASE:</b>	No		

Under the conditions specified, this permit authorizes the following:

**Article Category:** Plant Pathogens - Bacteria

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Pectobacterium carotovorum	Any	Research - Lab	VA	Unknown, ATCC 25270	C-15

**PERMIT GUIDANCE**

Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury (see <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx> for current country/regional listings) for current country listings.

This permit does not authorize importation, interstate movement, and/or environmental release of strains of genetically engineered regulated organisms (created by the use of recombinant DNA technology).

If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to [http://www.aphis.usda.gov/import\\_export/animals/animal\\_import/animal\\_imports\\_anproducts.sh](http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.sh) tml.

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife

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THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING  
PPQ HEADQUARTER OFFICIAL VIA EPERMITS.



**Jorge Abad**

DATE

**12/19/2017**

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, or your States Department of Agriculture to ensure proper permitting.

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

### PERMIT CONDITIONS

This permit authorizes the interstate movement of pure cultures containing *Pectobacterium carotovorum* as listed in the permit from researchers Virginia to Heinrich Jasper of Genentech, Inc, located at 1 DNA Way Room 12-268 South San Francisco, California 94080 for laboratory research. Experiments with the regulated article must be conducted in the inspected containment facility (CF) # 4592, and is subject to the additional conditions below.


1. The permit holder must:
  - (a) comply with all requirements and permit conditions,
  - (b) maintain a valid permit so long as the regulated organisms are alive,
  - (c) this permit cannot be assigned or transferred to other persons.
  - (d) permittee must maintain a residence in the United States
  - (e) safeguard and dispose of the regulated organisms during the term of this permit,
  - (f) take all necessary precautions to prevent the unauthorized release of regulated organisms. In the event of an unauthorized release, the permit holder must notify the permit unit,
  - (g) adequately mitigate environmental impacts resulting from unauthorized release of regulated organisms,
  - (h) contain any/all organisms not authorized under this permit,
  - (i) notify the permit unit of the receipt of unauthorized organisms,
  - (j) notify the permit unit if facilities are destroyed or decommissioned for any reason,
  - (k) maintain an official permanent work assignment at the address on this permit,
  - (l) notify the permit unit in advance of any change in the permit holder's work assignment,
  - (m) destroy all regulated organisms prior to departure unless other arrangements are confirmed by the permit unit prior to the permit holder's departure, and
  - (n) notify the permit unit of the destruction of regulated organisms.

Notifications to the permit unit must be made via 866-524-5421 or [pest.permits@aphis.usda.gov](mailto:pest.permits@aphis.usda.gov) within one business day of the event triggering a notification.

2. All persons working with these organisms must be informed of these permit conditions. Anyone working with these organisms must agree to and sign/ initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/ APHIS but must be readily accessible in the event of an inspection and presented upon request.

Note: these conditions may be copied and stored electronically for electronic signature and

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initialing provided that the permit number, authorized organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

3. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated organisms authorized under this permit.
4. Cultures must be transported in a securely closed, watertight container (primary container, test tube, vial, etc.) which must be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient non-particulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

Place a copy of this permit with all shipments.

5. Upon receipt, whenever possible, all packages must be opened within a laminar flow biosafety cabinet that meets or exceeds Class II, Type A, in or associated with the permit holder's assigned laboratory facilities within CF#4592 to ensure the shipment contains only permitted organisms and is free of contaminants. Cultures must be in sealed containers during transport to or within the permit holder's assigned research facilities.
6. All un-used and leftover organisms, and all packaging materials in contact with organisms and/or contaminants, shall be sterilized or destroyed immediately after removing regulated material.
7. All research activities must occur in laboratories within CF#4592 that have been inspected and found adequate for containment of the organisms received under this permit. Access to laboratories must be restricted to authorized personnel.
8. Organisms must be maintained or stored in the permit holder's research facilities within CF#4592. All stored organisms must be kept in a locked area with access restricted to authorized personnel.
9. This authorization is strictly for research in a controlled environment and is not valid if the organism(s) will be used in greenhouse, field research or will be released into the environment.
10. Upon completion of research, all organisms not retained for future use must be destroyed by heat or chemical treatment prior to disposal. All glassware and other materials used to conduct research must be decontaminated prior to reuse or disposal.

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11. If Autoclaving Waste:

- a. Waste must be autoclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of 30 minutes.
  - b. Autoclave tape or other indicators must be placed on each bag or sharps container prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
  - c. The autoclave log must be completed by each user for each autoclave cycle. All parameters must be noted as listed on the log for each autoclave load.
  - d. If the autoclave does not attain the minimum time and/or temperature or the autoclave tape does not change color, a notation must be made in the comment section of the autoclave log. The load must then be re-autoclaved after placing new tape on the material. If minimum time and temperature is not attained on the second cycle, users must contact the person responsible for maintaining the unit to initiate repairs. Waste must then be treated at the alternate autoclave facility.
  - e. Thermometers on the autoclave must be calibrated annually, and a written record must be maintained. Calibration must be done by an authorized autoclave service company during routine servicing.
  - f. Every 6 months, you must use a commercially available test indicator kit that uses bacterial spores *Bacillus stearothermophilus* that are rendered unviable at 250 degrees F or 121 degrees C. For the test, ampoules of *B. stearothermophilus* are autoclaved along with a load of waste. Upon completion of the cycle, the ampoules are incubated for 48 hours and then observed for any sign of growth, which indicates insufficient sterilization. If any growth is observed, you must have the autoclave serviced and retested.
12. There is to be no further distribution of these organisms without prior approval from State and Federal regulatory officials. A valid permit is required for movement of the regulated materials.
13. Under the Plant Protection Act, individuals or corporations who fail to comply with these conditions and authorizations, or who forge, counterfeit, or deface permits or shipping labels may receive civil or criminal penalties, and may have all current permits cancelled and future permit applications denied.

**END OF PERMIT CONDITIONS**

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